

ATTACHMENT 97

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF CALIFORNIA
3 SAN FRANCISCO DIVISION
4

5 - - - - -x
6 SURGICAL INSTRUMENT SERVICE COMPANY, INC.,
7 Plaintiff,
8 -against-
9 INTUITIVE SURGICAL, INC.,
10 Defendant.
11 - - - - -x

12 Virtual Zoom Deposition
13 March 10, 2023
14 9:00 a.m.

15
16 VIRTUAL VIDEO DEPOSITION of PHILIP J.
17 PHILLIPS, in the above-entitled action, held
18 at the above time and place, taken before
19 Jeremy Richman, a Shorthand Reporter and
20 Notary Public of the State of New York,
21 pursuant to the Federal Rules of Civil
22 Procedure, and stipulations between Counsel.
23

24 * * *

1 P. PHILLIPS

2 Q. Okay. Does -- but am I right 09:21:43
3 that statements that FDA officials made 09:21:46
4 on the topic of the regulatory status 09:21:49
5 of extending the uses of EndoWrists is 09:21:54
6 something that would impact your 09:21:57
7 opinions, correct? 09:22:00

8 A. Well, I would certainly 09:22:02
9 consider those in rendering opinions, 09:22:04
10 yes. 09:22:06

11 Q. Okay. And you didn't 09:22:06
12 consider any of the statements that FDA 09:22:08
13 officials made in submitting -- when 09:22:10
14 you submitted your opening report; 09:22:12
15 isn't that right? 09:22:15

16 A. Unless there's any opinions 09:22:16
17 here, and I don't recall off the top of 09:22:18
18 my head, unless there's any opinions 09:22:19
19 that actually reflected some statements 09:22:21
20 that reviewers or other FDA officials 09:22:23
21 had made, I would agree with your 09:22:26
22 statement. 09:22:28

23 Q. All right. So if I read your 09:22:28
24 report from front to back, and I don't 09:22:31
25 see you, see you referencing a 09:22:34

1 P. PHILLIPS

2 statement by an FDA official on the 09:22:36
3 topic of extending the usages of an 09:22:38
4 EndoWrist, then it's fair that, to 09:22:43
5 conclude you did not consider those 09:22:47
6 statements in forming your opinions in 09:22:48
7 this opening report? 09:22:50

8 A. Yes. 09:22:53

9 Q. Under Depositions, you have 09:22:53
10 listed two depositions, do you see 09:22:58
11 that? 09:23:02

12 A. Yes. 09:23:03

13 Q. Who is Mark Johnson and Ted 09:23:14
14 Clairborne in terms of their 09:23:17
15 affiliation? 09:23:18

16 A. I believe they're Intuitive 09:23:19
17 employees, I don't know their actual 09:23:22
18 titles. 09:23:23

19 Q. So in preparing your opening 09:23:26
20 report, you did not review the 09:23:29
21 deposition of Greg Posdal; is that 09:23:31
22 right? 09:23:37

23 A. I believe that's correct, I 09:23:37
24 did not. 09:23:38

25 Q. You did not review the 09:23:38

1 P. PHILLIPS

2 creating a code. 09:31:29

3 So the product code database 09:31:31

4 itself is quite a diverse group of 09:31:31

5 codes that have varied meaning 09:31:35

6 depending upon the actual reviewers, 09:31:37

7 for the most part reviewers and lower 09:31:41

8 level administrators that create them. 09:31:44

9 Q. In your consulting practice, 09:31:45

10 do you periodically look at the product 09:31:47

11 codes on FDA's website? 09:31:51

12 A. Yes. 09:31:55

13 Q. Why do you do that? 09:31:56

14 A. Because it does represent 09:31:57

15 groupings of devices, categorization of 09:31:59

16 devices. But again, with the 09:32:04

17 limitation that I understand that those 09:32:07

18 product codes are not terribly precise. 09:32:08

19 Q. And you know those product 09:32:10

20 codes have a category that says 09:32:13

21 "submission," right? 09:32:17

22 A. I'm a little confused with 09:32:19

23 what you're saying. 09:32:22

24 Q. Well, when you pull up, when 09:32:23

25 you go to that database, which you do 09:32:24

1 P. PHILLIPS

2 comply with FDA requirements, if at 10:27:40
3 all? 10:27:42

4 MR. MCCAULLEY: Objection to 10:27:44
5 form. 10:27:45

6 A. Well, I would want to be 10:27:45
7 aware of any product codes that are 10:27:48
8 being created. But again, that 10:27:49
9 wouldn't necessarily determine what my 10:27:52
10 advice would be. 10:27:54

11 Q. Why would you want to be 10:27:55
12 aware of the product codes that have 10:27:56
13 been created? 10:27:58

14 A. Well, you can just see that 10:27:59
15 again what a reviewer and administrator 10:28:01
16 at FDA have done, or how they perhaps 10:28:05
17 viewed a particular situation. Again, 10:28:08
18 I wouldn't necessarily believe that 10:28:10
19 that represents FDA's official position 10:28:12
20 because product codes are created very 10:28:14
21 informally. But I would like to be 10:28:17
22 aware of it. 10:28:19

23 Q. And let's say you did exactly 10:28:21
24 that. They told you what I told you 10:28:24
25 they wanted to do. And you went to the 10:28:27

1 P. PHILLIPS

2 down to whether they were making any 10:33:35
3 significant changes to the OEM's 10:33:37
4 device. That would be the determining 10:33:39
5 factor. 10:33:41

6 But there could be other 10:33:43
7 questions that could be raised as well 10:33:45
8 that would be extremely relevant to 10:33:48
9 making the decision as to whether a 10:33:50
10 510(k) is an appropriate filing. 10:33:52

11 Q. But what steps would you 10:33:56
12 take, would you recommend, for example, 10:33:58
13 that they go and consult any particular 10:34:00
14 regulation? 10:34:04

15 A. Well, again, it's more 10:34:07
16 complicated than we can just simply 10:34:08
17 talk about in a few minutes. In this 10:34:11
18 particular case, you have to determine 10:34:16
19 what activities the company is engaged 10:34:18
20 in and how FDA regulates those 10:34:20
21 activities. 10:34:23

22 If the company maintains that 10:34:25
23 they are simply doing servicing of a 10:34:26
24 device and returning it back to the 10:34:30
25 healthcare provider or the hospital and 10:34:31

1 P. PHILLIPS

2 that they've not made any significant 10:34:33
3 changes to the device, then that's one 10:34:35
4 particular path that you would have to 10:34:39
5 travel to develop the documentation to 10:34:40
6 support whatever the final position is. 10:34:44

7 If the company is making 10:34:45
8 significant changes to the device, if 10:34:47
9 they acknowledge that the changes they 10:34:49
10 made are significant, then they may be 10:34:52
11 either a remanufacturer or perhaps even 10:34:53
12 a manufacturer. And then there's a 10:34:56
13 whole other set of questions that have 10:35:01
14 to be asked because a significant 10:35:02
15 change could result in a nonsubstantial 10:35:04
16 equivalent determination and not being 10:35:06
17 eligible to go to market by way of a 10:35:08
18 510(k). 10:35:11

19 It depends upon the 10:35:13
20 circumstances and there's a lot of 10:35:15
21 different circumstances that could 10:35:17
22 affect an outcome of this type of a 10:35:20
23 situation. 10:35:21

24 Q. Why does it depend on the 10:35:22
25 circumstances? 10:35:24

1 P. PHILLIPS

2 A. What is the company engaged 10:35:25
3 in? Are they relabelling the product? 10:35:28
4 Are they offering the product for sale 10:35:31
5 as part of their catalog? Have they 10:35:34
6 made significant changes to the device? 10:35:37
7 All of these things are extremely 10:35:38
8 important decisions before you can 10:35:40
9 advise a client as to what it is that 10:35:43
10 they should actually do. 10:35:46

11 Q. And if the company comes to 10:35:47
12 you and says we're making a significant 10:35:50
13 change to an OEM's device, at that 10:35:52
14 point you need tell them they need to 10:36:02
15 get a 510(k); is that fair? 10:36:04

16 A. No, that's not fair. I would 10:36:07
17 question the basis for how they 10:36:09
18 concluded the change is significant. 10:36:11
19 If a company wants to be subject to 10:36:12
20 higher regulation than is required by 10:36:15
21 law, I've helped some companies do that 10:36:16
22 on occasion. But generally speaking 10:36:18
23 what I would first do is dive a little 10:36:24
24 deeper as to why they believe that a 10:36:26
25 particular change that they've made is 10:36:28

1 P. PHILLIPS

2 are very egregious examples that are so 11:47:12
3 clear. A company remanufactures to the 11:47:18
4 extent that the device doesn't look 11:47:19
5 anything like the original device. It 11:47:21
6 would have to be something very 11:47:23
7 extreme. Otherwise, I would suggest 11:47:25
8 responding and addressing the issues 11:47:26
9 and I do that quite frequently. 11:47:27

10 Q. What is the process, to your 11:47:29
11 knowledge, about how, that the FDA goes 11:47:31
12 through to get approval to, internally 11:47:35
13 to send an "It Has Come to Our 11:47:38
14 Attention" letter, do you know? 11:47:41

15 A. Well, there's, again, let me 11:47:42
16 tell you, there's been a recent 11:47:45
17 reorganization within CDRH, and Christy 11:47:47
18 Foreman is aware of that as well. So 11:47:51
19 we're both perhaps living a couple 11:47:53
20 years ago where it was a slightly 11:47:55
21 different organizational structure. 11:47:57

22 But the individuals that are 11:47:58
23 responsible for taking compliance 11:47:59
24 actions, they do have delegation of 11:48:01
25 authority. So not just anyone can send 11:48:04

1 P. PHILLIPS

2 one of those letters. 11:48:07

3 So that does represent the 11:48:07
4 views of the organization, but there 11:48:09
5 are ways of either challenging those 11:48:12
6 letters, they all have contacts and 11:48:14
7 dates associated with when you're 11:48:17
8 supposed to respond. And depending 11:48:18
9 upon what the outcome of that is, you 11:48:21
10 can always go to a higher level, appeal 11:48:24
11 any kind of a decision that FDA is 11:48:26
12 making. 11:48:28

13 Q. Does FDA today have the 11:48:29
14 authority to determine whether a 11:48:31
15 particular activity is remanufacturing? 11:48:33

16 A. Yes, they have the authority 11:48:39
17 to make that decision, yes. 11:48:40

18 Q. Okay. Did you see in the 11:48:41
19 course of your work in this matter any 11:48:43
20 "It Has Come to Your Attention" 11:48:45
21 letters? 11:48:47

22 A. Not that I recall. 11:48:47

23 Q. Would an "It Has Come to Your 11:48:49
24 Attention" letter being sent to Rebotix 11:48:54
25 change your opinions in this matter? 11:48:57

1 P. PHILLIPS

2 didn't mean to confuse you. 14:14:02

3 There's no application before 14:14:03

4 them, I understand, I have no problem, 14:14:06

5 you're saying the FDA would want to 14:14:08

6 know from the company why it thinks 14:14:10

7 they're engaged in servicing and what 14:14:15

8 it is they're doing, that's what you're 14:14:17

9 telling me, right? 14:14:18

10 A. Yes. 14:14:18

11 Q. Okay. And, but when it comes 14:14:19

12 time for FDA to decide is this activity 14:14:22

13 a significant change that brings it 14:14:25

14 into the realm of remanufacturing, the 14:14:27

15 FDA is going to look, is going to make 14:14:29

16 that decision based on the activities 14:14:32

17 that are actually being performed on 14:14:34

18 the device. 14:14:35

19 Do you agree with me on that? 14:14:36

20 A. Yes. 14:14:38

21 Q. Do you have tab 22 in front 14:14:38

22 of you? 14:14:45

23 A. That's not the one you 14:14:49

24 requested, right, it's still in the 14:14:51

25 box? 14:14:52

1 P. PHILLIPS

2 labeled REBOTIX175417 through 418. 16:23:19

3 (Exhibit 268, marked for 16:23:27

4 identification, Bates stamped 16:23:27

5 REBOTIX175417 through 418.) 16:23:28

6 A. I have that in front of me 16:23:28

7 now. 16:23:29

8 Q. Okay. This document you did 16:23:30

9 not review in advance of submitting 16:23:34

10 your opening expert report in this 16:23:39

11 matter, correct? 16:23:41

12 A. Yeah, I believe that's 16:23:42

13 correct. 16:23:43

14 Q. And I believe you cited it in 16:23:43

15 your rebuttal report, but let me just 16:23:47

16 look. 16:23:56

17 Yes, you included it in 16:23:57

18 Exhibit 1 in your rebuttal. 16:23:59

19 A. Okay. 16:24:01

20 Q. This is a letter dated 16:24:02

21 November 16, 2021, from Mark Trumbore 16:24:07

22 to Chris Gibson, Chief Operating 16:24:11

23 Officer, Rebotix Repair, LLC; is that 16:24:15

24 right? 16:24:19

25 A. Correct. 16:24:19

1 P. PHILLIPS

2 Q. And this is a "It Has Come to 16:24:19
3 Our Attention" letter, correct? 16:24:23

4 A. Yes. 16:24:25

5 Q. And that's a particular type 16:24:26
6 of FDA -- of letter that FDA uses in 16:24:27
7 certain circumstances, right? 16:24:30

8 A. Yes, it is. 16:24:32

9 Q. And what are the 16:24:33
10 circumstances when FDA decides to send 16:24:34
11 a "It Has Come to Our Attention" 16:24:37
12 letter? 16:24:39

13 A. Well, it's not an enforcement 16:24:39
14 action, it's really an opportunity have 16:24:43
15 a dialogue. I mean, obviously FDA has 16:24:44
16 some sort of a concern in order to 16:24:48
17 issue the letter, but they've not made 16:24:51
18 any kind of decisions at that time, 16:24:53
19 they're fact-finding and they want to 16:24:54
20 get actually more information from the 16:24:57
21 regulated company. 16:24:58

22 Q. And if you were advising 16:24:59
23 Rebotix at the time in November of 2021 16:25:01
24 when they received this letter, would 16:25:07
25 you advise they engage with FDA in 16:25:09

1 P. PHILLIPS

2 response to this letter? 16:25:12

3 A. Yes. 16:25:12

4 Q. And it says "It has come to 16:25:13

5 our attention that you may be 16:25:15

6 remanufacturing the da Vinci S 16:25:16

7 EndoWrist instruments." 16:25:19

8 Do you see that? 16:25:19

9 A. Yes. 16:25:20

10 Q. If you look at the third 16:25:20

11 paragraph, the third paragraph says 16:25:23

12 "Specifically the da Vinci S EndoWrist 16:25:25

13 instruments were cleared for a set 16:25:28

14 number of uses. By extending the 16:25:30

15 number of uses, your activities may be 16:25:32

16 altering the intended use of the 16:25:35

17 subject device." 16:25:37

18 Do you see that? 16:25:37

19 A. Yes. 16:25:38

20 Q. And then the FDA requests 16:25:47

21 that Rebotix provide information with 16:25:50

22 three bullet points. Do you see that? 16:25:51

23 A. Yes. 16:25:51

24 Q. And the first bullet point is 16:25:52

25 "FDA clearance or approval number for 16:25:54

1 P. PHILLIPS

2 the remanufactured da Vinci S EndoWrist 16:25:55

3 instruments." 16:25:59

4 Do you see that? 16:25:59

5 A. Yes. 16:26:00

6 Q. The second one is "Prior 16:26:00

7 submission numbers, if previously 16:26:04

8 withdrawn or found not substantially 16:26:05

9 equivalent, related to your activities 16:26:08

10 with the da Vinci S EndoWrist 16:26:10

11 instruments. 16:26:14

12 Do you see that? 16:26:14

13 A. Yes. 16:26:15

14 Q. And the third one is "The 16:26:15

15 basis for your determination of whether 16:26:16

16 or not you are required to obtain FDA 16:26:20

17 clearance or approval for the da Vinci 16:26:22

18 S EndoWrist instruments." 16:26:25

19 Do you see that? 16:26:26

20 A. Yes. 16:26:28

21 Q. Would you advise the company, 16:26:28

22 in this situation Rebotix, to provide 16:26:29

23 the basis for their determination of 16:26:33

24 whether or not they're required to 16:26:36

25 obtain clearance or approval for the 16:26:37

1 P. PHILLIPS

2 da Vinci S EndoWrist instruments? 16:26:42

3 A. Yes, I wouldn't ignore this 16:26:43
4 letter. 16:26:46

5 Q. Do you know whether SIS 16:26:46
6 received a letter like this? 16:27:01

7 A. I do not know. 16:27:04

8 Q. Did you see anywhere in the 16:27:05
9 files of anything you reviewed in this 16:27:12
10 matter where you saw that SIS made a 16:27:14
11 determination on whether or not it was 16:27:19
12 required to obtain FDA clearance or 16:27:20
13 approval to reset da Vinci S EndoWrist 16:27:22
14 instruments? 16:27:26

15 A. Well, I know that they 16:27:26
16 believed they were simply engaged in 16:27:28
17 repair activities. I'm not exactly 16:27:30
18 sure of internal documentation, is that 16:27:32
19 what you're asking about? 16:27:35

20 Q. Yeah. Did you see internal 16:27:36
21 documentation where they came to that 16:27:38
22 conclusion you're talking about? 16:27:41

23 A. No. 16:27:43

24 Q. In your box there should be a 16:27:44
25 tab 3, you might want to use the box 16:27:49

1 P. PHILLIPS

2 that type of a determination. 17:27:22

3 Q. So that statement is not 17:27:23

4 false and misleading? 17:27:25

5 A. Well, no, I believe it is 17:27:27

6 false and misleading to make those 17:27:29

7 types of statements. Because again, 17:27:30

8 what was the purpose of making the 17:27:34

9 statement? There's a point that's 17:27:35

10 being made, yes, the statement may look 17:27:37

11 relatively benign, but I think you need 17:27:39

12 to look at it in the complete context 17:27:41

13 of the overall communication. 17:27:43

14 Q. And did you look at the 17:27:44

15 overall communication in which this 17:27:45

16 statement was made? 17:27:46

17 A. No, I looked at what was 17:27:48

18 quoted from the complaint. 17:27:52

19 Q. And then the last one says in 17:27:52

20 this Paragraph 97, "Intuitive also 17:27:56

21 states that, quote, any modification to 17:27:59

22 allow for use of a da Vinci product 17:28:01

23 beyond its useful life exceeds the 17:28:03

24 scope of the original clearance by 17:28:05

25 expanding the FDA cleared indications 17:28:08

CERTIFICATION

I, JEREMY RICHMAN, a Notary Public for and within the State of New York, do hereby certify:

That the witness whose testimony as herein set forth, was duly sworn by me; and that the within transcript is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 19th day of March, 2023.

A handwritten signature in dark ink, appearing to read 'Jeremy Richman', with a long horizontal flourish extending to the right.

JEREMY RICHMAN

* * *